# Exhibit 11

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# Via Email

Special Master David Cohen Carol B. Stokes United States Courthouse 801 West Superior Avenue Cleveland, Ohio 44113-1837 david@specialmaster.law

Re: In re National Prescription Opioid Litigation, Case No. 17-md-2804 (N.D. Ohio): Time Limits and Allocation for Depositions of DEA Witnesses

Dear David:

In advance of our call with DOJ and Plaintiffs, I wanted to lay out the Defendants' position on the allocation of time for the DEA fact and 30(b)(6) witnesses. As you know, Defendants requested these depositions, which we view as among the most critical in the case, and spent considerable time and resources negotiating with DOJ the scope of DEA's document production and testimony authorization. Defendants have already compromised extensively on our discovery requests to reduce the burden on DOJ and DEA. Our initial *Touhy* request sought depositions of 15 current and former DEA employees, Federal Rule of Civil Procedure 30(b)(6) testimony on 24 topics, and 37 categories of documents. After months of negotiation, Defendants agreed to limit our requests to a subset of specific individuals and topics, and agreed to search terms that yielded a reasonable volume of responsive documents for review.

Once DEA authorized the depositions and began producing documents, the Plaintiffs suddenly insisted on having several hours to examine the defense-noticed witnesses themselves. The scope of discovery authorized by DEA as of today reflects substantial prior compromise by defendants, but the importance of these witnesses in our view limits our ability to compromise further. We have discussed the time allocation with the Plaintiffs and are at an impasse.

# **DEA Fact Witnesses:**

To date, DEA has authorized Joe Rannazzisi, Kyle Wright, Demetra Ashely, and Keith Martin to testify as fact witnesses on certain topics noticed by the Defendants. Several other fact witnesses remain under consideration by DOJ, and Defendants respectfully request that DOJ be

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directed to make an authorization determination with respect to Mr. Mapes and Dr. Sannerud by no later than February 28. Defendants believe we are entitled to—and will require—the full seven hours of testimony on the record with each DEA fact witness. Indeed, less than the full seven hours with these critical witnesses would be severely prejudicial to our ability to mount a defense to plaintiffs' claims. We are not aware of any case in which a court held that the non-noticing party was automatically entitled to half of the presumptive seven-hour time limit with a third party witness—particularly where, as here, only *Defendants* went through the time and expense of obtaining *Touhy* authorization for the testimony. To the contrary, courts require the non-noticing party—here, the Plaintiffs—to move for an order to extend the deposition, which requires a showing of good cause. *Syncora Guar. Inc. v. EMC Mortg. Corp.*, 2012 WL 12505608, at \*2 (N.D. Cal. Mar. 8, 2012) (where both parties argued third party witness was critical to their case, court ordered two-day deposition with seven hours for each party); *U.S. v. AT&T Inc.*, 2011 WL 13242960, at \*2 (D.D.C. Nov. 27, 2011) (where noticing party requires the full time allowed, non-noticing party may seek additional time by showing good cause).

Defendants drafted our *Touhy* requests with the expectation that we would have seven hours to examine each witness. To the extent that Plaintiffs' proposed three hours would be taken out of the Defendants' time, there is simply no way that we could fully examine each witness on every authorized topic in four hours. Nor would such an outcome be fair, given the importance of these witnesses to our defenses, as well as the work we did to secure the authorization for these depositions and the production of the witnesses' documents. Mr. Rannazzisi, Mr. Wright, and Ms. Ashley will testify regarding the fundamental issues in this case: their recollections of DEA's interpretation and understanding of Defendants' regulatory obligations under 21 U.S.C. § 823 and 21 C.F.R. § 1301.74(b), DEA's interactions with Distributors and Manufacturers, DEA's setting of national quota for controlled substances, and DEA's policies and procedures for using ARCOS data reported by defendants. Each defendant group (Manufacturers, Distributors, and Pharmacies) will want to question the witnesses on these key topics to ensure that issues related to its particular role are fully explored and addressed. Additionally, the witnesses will testify on topics of interest to specific defendant groups which will require significant time to explore. For example, Mr. Rannazzisi has been authorized to testify on general topics of interest to all groups, plus topics primarily of interest to Manufacturers (his role in establishing quotas and Defendants' alleged obligations to monitor third-party registrants) and Distributors (communications regarding what constitutes a "suspicious" order and requests for de-identified ARCOS data). From his appearances on 60 Minutes to his appearance in Judge Polster's courtroom in January of 2018 (at the invitation of the Plaintiffs' Executive Committee), Mr. Rannazzisi has played a central role in this litigation.<sup>1</sup> Defendants, frankly, will be hard pressed to complete their questioning in seven hours, and cannot agree to accept any less than that.

Defendants will coordinate and strive to avoid duplicative questioning of all the DEA witnesses, as we have done successfully throughout the discovery process. But testimony from

<sup>&</sup>lt;sup>1</sup> We also understand that Mr. Rannazzisi has been retained by certain plaintiffs as an expert witness.

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the DEA fact witnesses is too important to each of our cases to limit it to four hours, based on a last-minute demand by Plaintiffs for three full hours to conduct a preservation examination for trial. Defendants spent significant time and money to make these depositions happen. Now that DOJ has agreed to produce Mr. Rannazzisi, Mr. Wright, and Ms. Ashley, Plaintiffs should not be allowed to deprive Defendants of the time Defendants need to fully examine each of them.

### DEA 30(b)(6) Witnesses:

DEA has authorized <u>four</u> separate witnesses to provide 30(b)(6) testimony in response to various requests issued by both parties. We understand DOJ to be taking the position, based on the Deposition Protocol, that DEA's 30(b)(6) testimony, for all parties on all topics, should be limited to 14 hours. We respectfully submit that is incorrect and impractical under the circumstances. The time limitations imposed by the Deposition Protocol apply only to parties. Order Establishing Deposition Protocol at 12 (June 20, 2018) [Dkt. # 643] ("If a *party* designates two or more individuals across both notices, a fourteen (14) hour time limit is imposed."). Since DEA is not a party to this litigation, the usual application of the FRCP would dictate that Defendants are entitled to seven hours of testimony from each of the four DEA witnesses authorized to testify in response to Defendants' requests. Nor would applying the 14-hour limit make sense here, given that four different groups – Manufacturers, Distributors, Pharmacies, and Plaintiffs – will require time to examine the witnesses.

That said, we don't think a rigid seven-hour limit per witness necessarily makes sense, given the topics on which each witness has been designated to testify. Nor does a rigid 50/50 time allocation between Plaintiffs and Defendants, given that defendants requested testimony on more topics that cover a broad range of issues relevant, and at times unique, to multiple defendant groups. Plaintiffs' topics, by contrast, are generally duplicative of Defendants' topics (e.g., DEA's interpretation of 21 U.S.C. § 823 and 21 C.F.R. § 1301.74 and the establishment of quotas) or narrow in scope (e.g., enforcement actions and settlements with defendants and DEA's interactions with HDA). For example:

• Thomas Prevoznik, Associate Section Chief for the Pharmaceutical Investigations Division, has been authorized to testify on topics relating to DEA's interpretation and enforcement of 21 U.S.C. § 823 and 21 C.F.R. § 1301.74, including obligations to monitor third party registrants; guidance provided by DEA regarding what makes an order for controlled substances "suspicious" under 21 C.F.R. § 1301.74; DEA's practicing of notifying distributors when another distributor terminated its relationship with a customer due to the risk of diversion; and DEA's decision not to allow distributors access to de-identified ARCOS data prior to February 2018. Mr. Prevoznik has also been authorized to provide testimony on two additional topics requested by Plaintiffs. Given that Mr. Prevoznik will testify on key topics for all three Defendant groups plus the Plaintiffs, we expect that Mr. Prevoznik's deposition will require more than seven hours.

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- Stacy Harper-Avilla, Chief of the UN Reporting and Quota Section, has been authorized to testify regarding DEA's practices and procedures related to the establishment of procurement and production quotas for prescription opioids and DEA's high-level rationale for increasing those quotas from 1995 to 2018. These topics are of crucial importance to the manufacturer defendants and go to the heart of plaintiffs' claims, however, are potentially of less import to other defendant groups. As such, we do not expect to need more than seven hours on the record with Ms. Harper-Avila.
- <u>Donnetta Spears</u>, Diversion Program Manager, has been authorized to testify regarding actions taken by DEA to follow recommendations provided by GAO in three reports issued in 2015 and 2016, as well as DEA's guidance to registrants and requests for guidance from registrants relating to the topics in Plaintiffs' subpoena. Defendants expect to need far less than seven hours of testimony from Ms. Spears.
- <u>James Arnold, Chief DRL of the Diversion Control Division</u>, has been authorized to testify on DEA's interactions with HDA, as requested by plaintiffs. Given the narrowness of the topic, we also would expect this deposition to require far less than 7 hours.

Plaintiffs have not yet provided a firm position regarding the amount of time required for 30(b)(6) testimony, or how that testimony should be split. In Defendants' view, and in light of some of the specifics laid about above, it would seem to make the most sense to allow a flexible structure providing a fixed total number of hours per side, to be allocated logically among the authorized witnesses. Defendants have received authorization for three separate 30(b)(6) witnesses, and should be granted up to 21 hours of deposition time, to be allocated as the Defendants wish among the authorized witnesses. Plaintiffs received authorization for one additional 30(b)(6) witness, Mr. Arnold, plus authorization for limited additional testimony from Mr. Prevoznik (2 topics), Ms. Harper-Avilla (1 topic), and Ms. Spears (1 topic). We propose granting Plaintiffs up to 14 hours of deposition time (if they request it), to be allocated among the authorized witnesses. We believe that if you determine the total amount of time available to each side, we are likely to be able to reach agreement among the defense group, with the plaintiffs, and with the DOJ as to how best to allocate and schedule that time.

We look forward to discussing these issues with you, the PEC, and the DOJ on Tuesday.

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Sincerely,

/s/ Enu Mainigi

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